

K061880

AUG 15 2007

## 510(K) SUMMARY

### ISOtis Accell DBM Family of Products

#### SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

IsoTis OrthoBiologics, Inc.  
2 Goodyear  
Irvine CA 92618 U.S.A.

PHONE: (949) 855-7168

CONTACT PERSON: Karon Morell

DATE PREPARED: August 10, 2007

#### NAME OF DEVICE:

Accell Family of Products (Accell DBM 100, Accell TBM,  
A2i, and Accell Connexus)

#### COMMON OR USUAL NAME

Bone Void Filler

#### CLASSIFICATION NAME

21 C.F.R. § 888.3045 Resorbable calcium salt bone void  
filler device

#### PREDICATE DEVICES

DynaGraft II Paste and Putty (K040419)  
AlloMatrix® DBM Putty with inert carrier Sodium  
Carboxymethylcellulose (K040980)  
InterGro® DBM with inert carrier Lecithin (K031399)  
Osteofil Paste DBM with inert carrier Porcine Collagen  
(K043420)

#### INTENDED USE/INDICATIONS

The Accell Family of products are intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The products are indicated for use as bone graft extenders in the spine, extremities and pelvis, or as bone void fillers in the extremities and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

## **DEVICE DESCRIPTION**

Accell DBM family of products are used for orthopaedic bone grafting procedures. They are osteoconductive human allogenic demineralized bone filling materials for use as fillers for gaps or voids that are not intrinsic to the stability of the bony structure.

Accell DBM family of products are products that are manufactured using human donor demineralized bone and may contain up to 70% poloxamer reverse phase medium carrier (RPM). The demineralized bone is derived from human ground, cortical allograft bone. Poloxamer RPM is an inactive product ingredient that is utilized as a containing agent for the demineralized bone and provides appropriate product handling characteristics for the products.

The products of the Accell DBM family are comprised of the same DBM and RPM components as found in DynaGraft II Gel, FDA cleared under 510(k) number K040419 and Connexus cleared under 510(k)'s K050690 and K052098. In addition, the Accell DBM family of products may contain up to a maximum of 70% of RPM carrier. This is the concentration of RPM already cleared in DynaGraft II gel.

## **SUMMARY OF PERFORMANCE TESTING**

The poloxamer RPM granules used to prepare the carrier in two of the Accell DBM family of products are characterized to confirm the chemical composition. The carrier is analyzed for pH, physical characteristics and appearance. A resorption study has been performed to examine the rate and extent of carrier elimination in male adult rats.

Resorption of the DBM was demonstrated during rabbit animal studies. After 12 weeks, very little of the DBM could be detected and most had been remodeled.

Viral inactivation studies have been performed for the demineralization process in combination with terminal sterilization processing.

Several animal studies were performed on both Connexus and DynaGraft II Gel and were submitted as part of their original 510(k) submissions (K050690 and K040419). Additional animal studies have been performed and previously submitted in the 510(k) supplements, for the Accell DBM family of products. These studies included rabbit tibial critical size defects and rabbit spinal fusion studies.

These studies confirmed that the Accell products raised no safety or performance issues and are substantially equivalent to the predicate device, DynaGraft II Gel Demineralized Bone Matrix.

## **OSTEOINDUCTIVE POTENTIAL**

Each lot of DBM used to manufacture the Accell DBM family of products is tested for osteoinductive potential using an *in vitro* cell culture test. The *in vitro* cell culture assay has been validated to correlate to an athymic rat osteoinductive potential assay. It is unknown how osteoinductivity potential, measured via the *in vitro* cell culture or athymic rat assays, will correlate with human clinical performance.

## **VIRAL INACTIVATION VALIDATION**

The methods for processing of the DBM contained in the Accell Family of products were evaluated for their viral inactivation potential. A selected panel of viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable inactivation potential of the processing methods for a wide range of potential viruses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 15 2007

IsoTis OrthoBiologics, Inc.  
c/o Ms. Karen Morell  
Director Quality Assurance and Regulatory Affairs  
2 Goodyear  
Irvine, CA 92618

Re: K061880  
Trade Name: Accell Family of Products (Accell DBM 100, Accell TBM, A2i,  
and Accell Connexus)  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler devices  
Regulatory Class: Class II  
Product Code: MBP, MQV  
Dated: May 28, 2007  
Received: May 30, 2007

Dear Ms. Morell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

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applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with the last name being more prominent.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K061880

Device Name: Accell Family of Products (Accell DBM 100, Accell TBM, A2i, and Accell Connexus)

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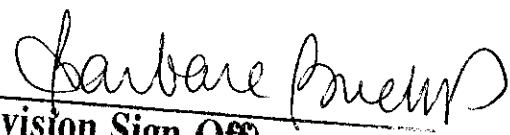
Prescription Use ☒  
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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